

Eppendorf Certificate

Certificate of Quality

BioBLU® Single-Use Bioreactor

The BioBLU® single-use bioreactors combine advantages of single-use technology with the performance and scalability of stirred-tank designs and can be applied to a wide variety of biological processes, including mammalian and stem cell cultivation as well as microbial fermentation. The BioBLU single-use bioreactors are intended to be used for Research and Development purpose only. Details see “Eppendorf Statement on Intended and Non-Intended Use of BioBLU® Single-Use Bioreactors”.

Quality Management System

The Eppendorf Quality Management System is certified according to ISO 9001, ISO 13485 and ISO 14001. A constantly high and reliable quality of products and processes covering the complete product lifetime is thereby established.

Environment and Production Process

BioBLU single-use bioreactors are manufactured in a controlled area and are subject to regular quality inspections. Manufacturing is continually monitored through stringent quality procedures. Consistent reliable quality of BioBLU single-use bioreactors is achieved by regular checks from the raw material to the final packed product.

Sterility and Endotoxins

Irradiation dose: min 25kGy [X-Ray]

Irradiation of BioBLU single-use bioreactors is carried out according to ISO 11137-2 with a SAL of 10^{-6} . Each lot is tested for the absence of endotoxins according to the European Pharmacopoeia as listed on the lot-specific report. For details, please refer to the lot-specific test report of the respective product.

Please note: The Sterility and Endotoxin statements are not applicable for the BioBLU® 3f bioreactor (order number: 1386000900) which is not delivered sterile and needs to be autoclaved prior usage.

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Additional Release Inspections

For each BioBLU single-use bioreactor, the following 100% inspections are carried out during manufacturing.

- Visual inspection
- Integrity test (pressure hold test)
- Agitation test

Statements

The following statements are valid for BioBLU single-use bioreactor components manufactured by or specifically for Eppendorf (vessel body, head plate, impeller and impeller shaft, pH spot holder, DO cap) as well as for the complete assembly process. On special request only, we may consent to supply additional information for third-party components, which is available for selected parts and products.

Biocompatibility

To the best of our knowledge, the raw materials used to produce the mentioned components of all BioBLU single-use bioreactors comply with USP Class VI <88> and / or respective sections of ISO 10993 standards.

Animal Derived Material – BSE / TSE

To the best of our knowledge, the raw materials of the mentioned components comply with EMA/410/01 Rev.3 (or equivalent regulatory requirements) for BSE / TSE mitigation.

Production Aides and Material Additives

To the best of our knowledge, the mentioned BioBLU components do not contain the following agents and the following agents are not intentionally added during the manufacturing process:

- Oleamide, Erucamide, Stereamides
- Tris(2,4-di-tert-butylphenyl)phosphite (tDtBPP, Irgafoss® 168)
- Biocides
- Plasticizers (including phthalates)
- Latex
- Antistatic agents
- Metallic dyes
- Mineral oil

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This certificate is valid for the following BioBLU® versions (order numbers)


Product ID	Product description
1386162000	BioBLU® 50c, micro, 1 Imp, pH, X-Ray
1386163000	BioBLU® 50c, macro, 1 Imp, pH, X-Ray
1386150000	BioBLU® 14c, micro, 1 Imp, pH, X-Ray
1386151000	BioBLU® 14c, macro, 1 Imp, pH, X-Ray
1386140300	BioBLU® 10c, micro, 1 Imp, pH, X-Ray
1386141300	BioBLU® 10c, macro, 1 Imp, pH, X-Ray
1386130000	BioBLU® 5c, micro, 1 Imp, pH, X-Ray
1386131000	BioBLU® 5c, macro, 1 Imp, pH, X-Ray
1386130500	BioBLU® 5p, micro, 1 Imp, pH, X-Ray
1386131500	BioBLU® 5p, macro, 1 Imp, pH, X-Ray
1386124000	BioBLU® 3c, micro, 1 Imp, pH, X-Ray
1386125000	BioBLU® 3c, macro, 1 Imp, pH, X-Ray
1386126000	BioBLU® 3c, micro, 2 Imp, pH, X-Ray
1386127000	BioBLU® 3c, macro, 2 Imp, pH, X-Ray
1386111000	BioBLU® 1c, 1 Imp, X-Ray
1386111100	BioBLU® 1c, 2 Imp, X-Ray
1386112000	BioBLU® 1c, 1 Imp, pH, X-Ray
1386112100	BioBLU® 1c, 2 Imp, pH, X-Ray
1386113000	BioBLU® 1f, 2 Imp, X-Ray
1386113100	BioBLU® 1f, 3 Imp, X-Ray
1386101000	BioBLU® 0.3c, 1 Imp, X-Ray
1386101500	BioBLU® 0.3c, 1 Imp, pH, X-Ray
1386101100	BioBLU® 0.3f, 2 Imp, X-Ray
1386102000	BioBLU® 0.3sc, 1 Imp, pH, X-Ray
9111035110	BioBLU® 5c, micro, 1 Imp, pH, S, C1
9111035153	BioBLU® 14c, macro, 1 Imp, pH, S, C3
9111035145	BioBLU® 50c, 1 Imp, pH, S, C3
9111035170	BioBLU® 5c, 1 Imp, S, C6
9111035161	BioBLU® 14c, 1 Imp, S, C6
9111035188	BioBLU® 50c, 1 Imp, S, C6
9111035226	BioBLU® 3c, 1 Imp, pH, S, C8
9111035234	BioBLU® 14c, 1 Imp, pH, S, C8
9111035242	BioBLU® 50c, 1 Imp, pH, S, C8
9111035218	BioBLU® 50c, micro, 1 Imp, pH, S, C9
9111035285	BioBLU® 50c, macro, 1 Imp, pH, S, C14

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ISO 9001
Certified

ISO 13485
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ISO 14001
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